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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,173	04/14/2000	Norihisa Ooe	2185-0424-SP	8838
7590 01/24/2008 Birch Stewart Kolasch & Birch LLP P O Box 747 Falls Church, VA 22040-0747			EXAMINER MITCHELL, LAURA MCGILLEM	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/550,173

Applicant(s)

OOE ET AL.

Examiner

Laura M. Mitchell

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-9,11-16,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-9,11-16,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It is noted that claims 1, 9, 11-16 have been amended, claims 2, 3, 5, 10 and 17-29 are cancelled and claims 30-31 are newly added. Claims 1, 4, 6-9, 11-16 and 30-31 are under examination.

Sequence compliance

In the previous Office action, mailed 12/20/2006, the claims 22 and 24 were objected to because they contained sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). This objection had been raised as a result of the amendments of the claim 22 which recites the phrase "a nucleotide sequence from 33 base upstream to 15 base downstream of the transcription initiation point in the 5' upstream region of mouse metallothionein I gene" and claim 24 which recites the phrase "a nucleotide sequence from 50 base upstream to 10 base downstream of the transcription initiation point in the 5' upstream region of chicken ovalbumin gene". It is noted that claims 22 and 24 have been canceled in the most recent amendment and the objection is moot.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4 and 6-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 4 and 6-9 are drawn to animal cells, but do not specify that the cells are isolated animal cells. As the claim is written, it encompasses *in vivo* human tissue. Claims to *in vivo* human tissue are non-statutory because the claims read on part of a living human being *in situ*. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated " or "purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 has been cancelled, therefore the rejection of claim 19 under 35 U.S.C. 112, first paragraph, (written description) as detailed in the Office action mailed 12/28/2006 pages 9-10) is moot.

Claims 1, 4, 6-9 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. It is noted that claims 2-3, 5, 17 and 19-29 have been canceled, therefore the rejection is mooted for claims 2-3, 5, 17 and 19-29. It is noted that the claims have been amended to narrow the breadth of ligand-responsive transcription control factor and the word "gene". In addition the claims have been amended to remove recitation of the exclusion of the gene c), a "cell number reporter gene". However on further consideration this rejection is being maintained for reasons of record in the previous Office Action, mailed 12/28/2006 and for reasons outlined below.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Scope of the claims. The claims are drawn to a stably transfected animal cell, a method of making the animal cell and methods of using the cell to screen agents for modulating the transcription activity of a ligand responsive control factor. The claims are drawn to any animal cell which is expressing a ligand -responsive transcription control factor that is an aryl hydrocarbon receptor, estrogen receptor, androgen receptor or thyroid hormone receptor. This would encompass cells that are expressing transcription control factors either endogenously or exogenously. Since the claims can

encompass any cell from any animal, this constitutes a large genus of cells expressing the ligand -responsive transcription control factor as claimed.

The cell comprises polynucleotides (a) and (b). Polynucleotide (a) is comprised of several elements: a recognition sequence of the ligand -responsive transcription control factor operably linked to a sequence encoding a reporter protein, and a minimum promoter. The genus of polynucleotide (a) is large for several reasons. Although the recitation of minimal promoter has been further limited to include the sequence of SEQ ID NO:5, the phrase recites "minimum promoter comprising the nucleotide sequence of SEQ ID NO:5 and therefore encompasses a promoter with other elements such as enhancers and repressors. As the claim is written, the minimal promoter does not have to be operably linked to the sequence encoding the reporter protein or the ligand -responsive transcription control factor. Although recognition sequences of the recited ligand -responsive transcription control factor/elements are known in the art (e.g. ERE, ARE, DRE), the recitation encompasses any portion of that recognition sequence including partial portions or flanking regions of the recognition sequence. Therefore the scope of polynucleotide (a) is very broad.

Polynucleotide (b) is comprised of a promoter operably linked to a selective marker protein. The scope of the promoter encompasses weak or strong promoters and those with additional enhancer or repressor sequences. The phrase "selective marker" has not been given a limiting definition in the specification and therefore can be given the broadest reasonable interpretation and is not limited to sequences encoding antibiotic resistance proteins in the independent claims. Since many methods can be

used to select cells expressing marker proteins such as immunomagnetic separation, a selective marker encompasses a genus of any protein that can bind a specific antibody. Furthermore the claim does not place any functional limitation on polynucleotide (b) comprising a promoter and a selective marker. In addition as claim 1 is written, it encompasses a stably transformed cell in which polynucleotides (a) and (b) were on separate vectors or on the same expression vector. Therefore the claimed cell encompasses a very large genus of cells comprising polynucleotides (a) and (b). Although claim 9 is drawn to a cell that expresses an aryl hydrocarbon receptor and an Arnt receptor, it still encompasses polynucleotides (a) and (b) with the same breadth as described above.

The claims are also drawn to a method of obtaining/making the cell as claimed for the purpose of measuring the ability to control activity of a ligand responsive transcription control factor. These claims encompass obtaining the large genus of cells. Claims are also drawn to methods of using the cell to screen chemical substances that have modulating activity over transcription promoting activity of the ligand-responsive transcription control factor.

Nature of the invention. The nature of the invention is cells and methods to modulate complex signal transduction pathways to screen agents, which is a complex and unpredictable aspect of cell and molecular biology.

State of the Art. As written the claims encompass multiple ligand responsive elements, which are part of complex signal transduction pathways. Regarding the estrogen receptor, for example, Zhang et al (Comp Biochem Physiol A Mol Integr

Physiol. 2006 Jul;144(3):306-15.) reviews estrogen receptor signaling. Zhang et al teach that steroid hormones and other hormones acting through hormone receptors in the steroid superfamily also activate many of the same intracellular signaling cascades which provides the basis for extensive cross talk networks between hormones (see abstract and page 311 Figure 2). Therefore it is known in the art that the ligand responsive signaling cascades and gene expression is complex.

Amount of guidance provided/ Working examples. The specification discloses plasmids comprising thyroid hormone receptor responsive element (e.g. pGL3-TATA-TRE5-BSD) comprising a TATA box promoter and response elements from thyroid hormone receptors α or β . The specification also discloses a plasmid comprising an androgen receptor responsive element (e.g. pGL3-TATA-MMTV). The specification also discloses a plasmid comprising an estrogen receptor responsive element (e.g. pGL3-TATA-ERE). Applicants provide an example of luciferase reporter assay using T3 as the chemical substance on a Hela cell comprising the specific plasmid pGL3-TATA-TRE5-BSD in a thyroid hormone receptor (see Figures 5 and 6). The specification does not provide examples of using any other cells for a screening method or a specific example of using any other chemical substance besides the T3 thyroid hormone receptor binding protein in a reporter assay.

Unpredictability of the art. The unpredictability of being able to make and use a cell as claimed for a method to screen chemical agents is manifested in part in the complexity of signal transduction pathways and the breadth of the claimed cell. In order to practice the method as claimed it appears that the skilled artisan would have contact

the cell with some agent that would have to bind first to the ligand-responsive transcription control factor which would be a cell surface receptor. The basic activity of the ligand-responsive transcription control factor would be that it would be able to bind to the polynucleotide comprising a specific recognition sequence for that ligand-responsive transcription control factor. It appears that the binding of the transcription control factor to the recognition sequence would drive the expression of the reporter protein. However, this constitutes assaying ligand responsive signal transduction pathways which are known to be complex and often comprise duplicate pathways and feedback mechanisms. Absent evidence to the contrary, at least some of the cells that are encompassed by the claims will have endogenous levels of the ligand responsive transcription control factor such as estrogen receptor or thyroid hormone receptor. The specification discloses that the screening methods can include step of contacting the cell with the natural ligand of the ligand-responsive transcription control factor (i.e. receptor) with a chemical substance to be screened, or an embodiment in which there is a step of contacting the cell with the chemical substance to be screened without the natural ligand (see page 60, for example). Therefore, contacting the cell with a potential agonist and antagonist would likely affect endogenous pathways by binding to endogenous recognition sequences as well as those of polynucleotide (a). There is a potential for false positive and false negative results to the screening method. Therefore, given the breadth of the cell to be used, the ability to accurately determine whether a chemical substance has agonist or antagonist activity is unpredictable. The

skilled artisan would have to practice undue and excessive amounts of trial and error experimentation in order to make and use the claimed invention.

Level of skill in the art. Although the skill in the art is high, given the nature of the invention, the scope of the claims, state of the art, unpredictability of the art and lack of sufficient guidance and working example, the skilled artisan would have to practice undue and excessive trial and error experimentation in order to practice the claimed method.

Given the above analysis of the factors which the Courts have determined are critical in ascertaining whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have practiced undue and excessive experimentation in order to practice the claimed invention.

Claims 1, 4, 6-9 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that claims 2-3, 5, 17 and 19-29 have been canceled therefore the rejection is mooted for claims 2-3, 5, 17 and 19-29.

Response to Arguments

The limitations of the remaining claims have been narrowed so that the ligand-responsive transcription control factors are limited to one of aryl hydrocarbon receptor,

estrogen receptor, androgen receptor or thyroid hormone receptor. The specification discloses some known recognition sequences of these transcription control factors such as estrogen response elements (ERE), androgen response elements (ARE), TRE and DRE (see page 16). The claim limitations do not include specific sequences; therefore the limitation of "transcription factor recognition sequence" can be given the broadest reasonable interpretation. The minimum promoter has been further limited so that it comprising the nucleotide sequence of SEQ ID NO:5.

It is noted that the limitations regarding the gene described in c) lines 13-18 and its required absence from the claimed cells have been removed. The instant specification, the nucleotide sequence recited in c) is identified as the "cell number reporter gene" see page 25-26. The specification discloses that a cell comprising the "cell number reporter gene" would have to be the result of an operation to introduce the "cell number reporter gene". **However on further consideration this rejection is being maintained for reasons of record in the previous Office Action, mailed 12/28/2006 and for reasons outlined below.**

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, the specification discloses cells and plasmid comprising response elements for the claimed cell. The function of the cell as claimed is to measure the ability to control the activity of a ligand responsive transcription control factor.

The specification discloses plasmids comprising a TATA box promoter and a thyroid hormone receptor responsive element (e.g. pGL3-TATA-TRE5-BSD) comprising and response elements from thyroid hormone receptors α or β , or an androgen receptor responsive element (e.g. pGL3-TATA-MMTV) or an estrogen receptor responsive element (e.g. pGL3-TATA-ERE). As detailed in the above rejection, the claimed encompass a broad genus of cell and polynucleotides included in those cells

In the specification, there is no description of how the structure of the disclosed cell comprising the polynucleotide relates to the structure of the genus of cell encompasses by the claims. The genus would be expected to have divergent functional properties as small changes in polynucleotide sequences and promoters can have significant effects on the structure and properties of the cells and reporter constructs. The applicant does not provide an indication of how the cells and expression vectors disclosed is representative of other cells with the function of being useful for the screening methods. Therefore, there is not a structural and functional basis provided by the prior art or the specification for one of ordinary skill in the art to envision all cells as claimed.. According to these facts, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member

of this genus is not representative of the variant of the genus and is insufficient to support them.

Claims 1, 4, 6-9, 11-16 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 1, 9 and 14 have been amended to recite the phrase "a minimum promoter comprising the nucleotide sequence of SEQ ID NO:5". However the specification discloses SEQ ID NO:5 only as an oligonucleotide for use in a DNA synthesis reaction to construct a nucleotide sequence known as TATA DNA, which is the used to make the constructs used in cells and method of the invention.

While it is possible that the molecular biology steps taken to construct the polynucleotides to be used in the claimed cell might produce a polynucleotide comprising the exact sequence of SEQ ID NO:5, there is no specific support in the disclosure for a cell comprising a polynucleotide comprising a minimum promoter comprising SEQ ID NO:5. The specification names the expression vector constructs (e.g. pGL3-TATA-ERE5) but does not disclose the specific sequences of these constructs. It should be noted that this is not a requirement to disclose the entire sequence of the vectors used in the cell. However, since this information is not present

in the specification, there is no support for claiming cells comprising expression constructs with specific nucleotide sequences of SEQ ID NO:5. Therefore the amendment to the claims regarding "a minimum promoter comprising the nucleotide sequence of SEQ ID NO:5" constitutes impermissible new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant's amendments and arguments, see REMARKS (page 9), filed 11/7/2007, with respect to claims 11-12 and 14 have been fully considered and are persuasive. The rejection of claims 11-12 and 14-16 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn. It is noted that claims 22, 24 and 27-29 have been cancelled and therefore their rejection is moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's arguments, see REMARKS (pages 12-13), filed 11/2007, with respect to claims 1 and 13-14 have been fully considered and are persuasive. It is noted that

claims 2, 5, 17 and 25-28 have been cancelled, therefore their rejection is mooted. The claims have been amended so that the control factor is one selected from an aryl hydrocarbon receptor, an estrogen receptor, an androgen receptor or a thyroid hormone receptor. Mader and White teach a vector comprising glucocorticoid response element but does not specifically teach those from aryl hydrocarbon receptor, an estrogen receptor, an androgen receptor or a thyroid hormone receptor. Mader and White teach a vector with a promoter comprising a TATA region but do not teach a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. The rejection of claims 1 and 13-14 under 35 U.S.C. 102(b) as anticipated by Mader and White has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's amendments and arguments, see REMARKS (pages 13), filed 11/2007, with respect to claims 1, 3-4, 6-9, 11 and 14-16 have been fully considered and are persuasive. It is noted that claims 5 and 17 have been cancelled, therefore their rejection is mooted. The claims have been amended so that the control factor is one selected from an aryl hydrocarbon receptor, an estrogen receptor, an androgen receptor or a thyroid hormone receptor. Bradfield et al do teach the aryl hydrocarbon

receptor and the DRE recognition sequence, but do not teach a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. The rejection of claims 1, 3-4, 6-9, 11 and 14-16 under 35 U.S.C. 103(a) as being unpatentable over Bradfield et al (US Patent No. 5,650,283; of record) in view of Waldman and Waldman (of record) has been withdrawn.

Applicant's amendments and arguments, see REMARKS (page 13), filed 11/5/2007, with respect to claims 1-9, 11-12 and 14-17 have been fully considered and are persuasive. It is noted that claims 2, 3, 5 and 17 are cancelled. Bradfield et al do teach the aryl hydrocarbon receptor and the DRE recognition sequence, but do not teach a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. The rejection of claims 1, 4, 6-9, 11-12 and 14-16 under 35 U.S.C. 103(a) as being unpatentable over Bradfield et al (of record) in view of Waldman (of record) and further in view of Kushner et al (US Patent 6,117,638; of record) has been withdrawn.

Applicant's amendments and arguments, see REMARKS (page 14), filed 11/5/2007, with respect to claims 1, 3-9, 11, 14-17 and 19 and 21, 25-29 have been fully considered and are persuasive. It is noted that claims 2, 3, 5, 10 and 17-29 are cancelled. Bradfield et al do teach the aryl hydrocarbon receptor and the DRE recognition sequence, but do not teach a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. The rejection of claims 1, 4, 6-9, 11, and 14-16 under 35 U.S.C. 103(a) as being unpatentable over Bradfield et al (of record) in view of Waldman (of record) and further in view of O'Malley et al (US Patent 5,834,213; of record) has been withdrawn.

It is noted that claims 17-29 are cancelled which moot rejection of claims 20, 22 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mader et al (US Patent No. 5,512,483; of record) in view of Carter et al (*P.N.A.S.* 81:7392-7396, 1984).

Conclusion

No claims are allowed. SEQ ID NO:5 is not found in the prior art.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Laura M. Mitchell
Examiner
1/19/2008

/Joseph Woitach/
Joseph Woitach
SPE 1636